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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/826,618

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Jian Cao

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

08/22/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/826,618	<b>Applicant(s)</b> CAO ET AL.	
	<b>Examiner</b> MICHAEL KAHRELIN	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/8/2008 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner was unable to find support on page 22, lines 1-15 for the negative limitation "only." Any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under

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35 USC 112, first paragraph, as failing to comply with the written description requirement (See MPEP 2173.05(i)).

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. In regards to claims 1 and 10, it is unclear to what the second collected events are being compared in the second to last clause of the claim.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al. (US 2002/0183637, hereinafter “Kim”).

9. In regards to claims 1 and 10, Kim discloses a device/method for generating a template of a normal heartbeat comprising detecting a plurality of heartbeats (par. 0007-0010), collecting a first predetermined number of detected non-paced heartbeats having predetermined characteristics (via Figs. 4 and 6), generating a current template from the first selected events, waiting a predetermined delay (par. 0064), collecting a second predetermined number of detected non-paced heartbeats, determining whether the

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template is valid based on a comparison of only the collected second selected events (with the existing template; Fig. 6, “If a Template exists, correlate it with the next 21 template beats” block), and generating an updated template if the current template is not valid (par. 0010 and Fig. 6) from only the collected second beats (Fig. 6; “If not correlated” path). Please note that, although an embodiment utilizes paced and non-paced beats to determine “regularity”, these paced beats are not used for template generation, per the rules of paragraph 0078 and 0081. Further, Kim discloses an embodiment without therapy provision per paragraphs 0065 (“monitor mode”) and 0041 (“only monitoring of cardiac activity is performed”). As such, all beats are inherently non-paced because no pacing therapy is provided.

**10.** In regards to claims 2 and 11, the template update is repeated (par. 0064).

**11.** In regards to claims 3 and 12, identifying events as first selected events comprises determining whether consecutive events have a first characteristic (i.e. comprise the first 20 beats) and identifying a predetermined number of subsequent events as second selected events (i.e. comprise the beats subsequent to the 20 beats).

**12.** In regards to claims 4 and 13, the “monitoring only” embodiment requires that consecutive events have an RR-interval greater than a threshold per paragraph 0071. Further, the “NSR” beats of paragraphs 0078-0081 are consecutive to each other (although they may or may not be consecutive with respect to all heart beats) and have RR-intervals greater than a threshold because they must pass the “regularity” test of 0071.

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**13.** In regards to claims 7, 8, 16 and 17, a cross-match is determined and compared to a threshold and a delay is generated if the threshold comparison fails (par. 0108).

**14.** In regards to claims 9 and 18, R-R intervals associated with the first events are compared to an average (par. 0071); a cross-match is computed (par. 0105) if the R-R intervals are greater (or less) than the average; and a template is generated from the events corresponding to the cross-matches (par. 0108).

**15.** In regards to claims 5, 6, 14, 15, and 19, Kim discloses that valid sense events having first and second characteristics comprise the following characteristics: the sense event is not a ventricular pace event (par. 0078), the event has an R-R interval greater than a predetermined rate of about 600 ms (par. 0071), the sense event can comprise events other than those directly following a ventricular pace (par. 0078), and the ventricular sense event follows an atrial pace event by a predetermined threshold (par. 0081, rule 5) and is about 100 ms (see Fig. 9,  $\frac{1}{2}$  of the 320 ms window is the threshold).

### ***Response to Arguments***

**16.** Applicant's arguments filed 4/8/2008 have been fully considered but they are not persuasive. Applicant argued that Kim discloses a "beat-by-beat operation and there is no need to store multiple beats," thus fails to disclose determining whether a current template is valid based upon a comparison of only predetermined number of second collected events and updating an updated template from only second collected events. However, nothing in the claim language excludes a beat-by-beat operation. Even on a beat-by-beat basis, Kim's invention meets the claim language because there is a predetermined number of beats (21 beats) and they are "collected" (to be analyzed),

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even if individually. The Examiner maintains the position of the last Office Action of the "first" events being those generated in a template creation via Figs. 4 and 6, and the "second" events being those of Figure 6, initiated by a repeat of the algorithm of Figure 4, per paragraph 0064. The template is validated based on a comparison of "only the collected second selected events" (from the "second run" through Figure 6) with the first events (the existing template). In other words, the Examiner is of the position that the claim language "only" does not exclude a comparison between the second and first events because this is a comparison of the first events with *only* the second events.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHRELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/  
Primary Examiner, Art Unit 3762

/Michael Kahelin/  
Examiner, Art Unit 3762